REMARKS

I. STATUS OF THE CLAIMS

Claims 1, 4, 5, 8, 9, 12, 16, 18-20, 25, 27-29, 31, 64, and 87-88 are pending. No claim is amended herein.

II. REJECTIONS UNDER 35 U.S.C. §103

The Examiner has rejected claims 1, 4, 5, 8, 9, 12, 16, 18-20, 25, 27-29, 31, 64, and 87-88 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,572,873 to Osman et al. (*Osman*).

Applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness because *Osman* does not teach or suggest all the claim limitations and the Office has not identified a sufficient rationale that would motivate one of ordinary skill in the art to combine or modify the teachings of *Osman* to arrive at the claimed invention. *See* M.P.E.P § 2141.

Osman is silent as to the viscosity of the liquid phase of the foam, while the present invention requires "at least one viscosity enhancing agent, the liquid phase having a viscosity ranging from 2cP to 5 cP," as claimed in claim 1. *Osman* does mention stabilizing agents, including glycerol, as optional components. However, *Osman* also cautions that while addition of glycerol "imparts a longer half-life to the resultant foam[,] . . . glycerol also produces a tendency for the meshes to block up." *See Osman*, col. 13, ll. 15-19. The Office attempts to correct this deficiency of Osman by pointing to *Osman's* mention of stabilizing agents as possible optional components in support of its argument that "*Osman* et al. teach foams containing glycerol." *See* Office

Action, page 15. Additionally, the Office states that glycerol "inherently produces a viscosity of the liquid phase between 2cP and 5cP since it is the same viscosity agent that Applicant uses. At worst, one skilled may need to vary the amount of glycerol but . . . it would be obvious to vary." *See id*. Applicants respectfully disagree. The addition of glycerol does not inherently produce a viscosity ranging from 2cP and 5cP, as recited in claim 1. Moreover, the modification of *Osman* to produce the claimed foam with a viscosity ranging from 2cP and 5cP is not the result of routine optimization or experimentation for at least the reason that *Osman* provides no guidance as to what one of skill in the art would optimize. *See* M.P.E.P. § 2144.05

First, the addition of glycerol to the liquid phase of *Osman* does not inherently produce a viscosity ranging from 2cP and 5cP, as recited in claim 1. The viscosity of the liquid phase will vary depending on the precise composition of the liquid phase, including the sclerosing agent and the amount of glycerol that is present. Specifically, the viscosity of the liquid phase will depend at least in part on the sclerosing agent, the amount of glycerol added, and the ratio of glycerol to sclerosing agent..

Second, the modification of *Osman* to produce the claimed foam with a viscosity ranging from 2cP and 5cP is not the result of routine optimization or experimentation. The Office states that "[t]he foam density preferred by Osman et al. is between 0.07 g/ml and 0.19 g/ml . . . with a half life of at least 2 minutes. *See* Office Action, page 16. But, the Office has not identified any motivation that would lead one of ordinary skill in the art to modify *Osman* to arrive at the claimed foam with a liquid phase with a viscosity ranging from 2cP to 5cP. There are simply too many potential parameters to

vary given the general guidance and broad disclosure of *Osman*. *See Medichem S.A. v. Rolabo S.L.*, 437 F.3d 1157, 1167 (Fed. Cir. 2006). Specifically, there are six claim elements (variables) that are interrelated: amount of sclerosing agent, amount of viscosity enhancing agent, density, viscosity, half-life, and composition of the gas phase. Only using impermissible hindsight would one of skill in the art know how to optimize so many variables.

The Office states that *Osman* discloses that the "[a]ddition of glycerol to the composition imparts a longer half-life to the resulting foam. *See* Office Action, page 11. But, the density and half-life of the resulting foam are also dependent on the composition of the gas phase of the foam. *See* as-filed specification, Table 15, pages 91-92. Additionally, Applicants note that "[t]he addition of a viscosity enhancing agent, however, while increasing the half-life of a CO2 foam, also increases the density of the foam. Too high of a density can hinder a foams [sic] ability to displace blood and therefore be an effective foam for sclerotherapy. See as-filed specification, page 13, lines 16-19. *Osman* is silent as to both of these considerations.

For example, Table 15 of the as-filed specification reports the density and half-life of foams made with 100% CO_2, 100% O_2, 75% CO_2 / 25% O_2, and air with either 0%, 5%, 25%, or 40% glycerol. *See* as-filed specification, paragraph [0462], page 90. Table 15 shows that the addition of glycerol to the liquid phase produces different density and half-life values in the resulting foams depending on the gas composition of the foam. *See id*. For example, the addition of 5% glycerol to a 100% O_2 foam resulted in density values of 0.18 g/mL and half-life values of 144 and 140 seconds. *See* id. In

contrast, the addition of of 5% glycerol to 100% CO_2 foam resulted in density values of 0.24 and 0.20 g/mL and half-life values of 57 and 66 seconds. *See id*. These results demonstrate that the percentage of glycerol required to achieve particular density and half-life values in the resultant foam depends on the precise gas composition of the foam and that the density, half-life, and viscosity are all interrelated and a function of amounts of glycerol and sclerosing agent and gas composition.

In view of this fact, the Office has not identified, and *Osman* does not provide, sufficient guidance or motivation to arrive at the claimed viscosity ranges while maintaining the other claimed elements through routine experimentation or optimization. Rather, *Osman* mentions a broad range of potential gas phase components, one of which contains $C0_2$ from 10-90%. *Osman* also discloses the use of O_2 and other "physiologically blood dispersible gases," which is defined as a gas that is capable of being substantially completely dissolved in or absorbed by blood. *See Osman*, column 4, lines 51-53. Further, *Osman* states that "in one preferred form the gas used is a mixture of carbon dioxide and other physiological gases, . . . most preferably 30 to 50% carbon dioxide. *See Osman*, column 5, lines 59-63. Indeed, the Office acknowledges that "Osman et al. does not exemplify a composition in which the gas phase comprises at least 90% CO2," as claimed in claim 1, as amended. *See* Office Action, page 13.

Osman does not provide and the Office has not identified any motivation that would lead one of skill in the art to seek to modify *Osman* to arrive at the foams of the present invention that require at least 90% carbon dioxide and viscosity of the liquid phase ranging from 2cP to 5cP. As described in Applicants' specification, the amount of

glycerol (and associated viscosity of the liquid phase) required to achieve the claimed density and half-life values is dependant on the precise gas composition of the foam. Therefore, the modification of *Osman* in an attempt to produce the claimed gas composition and viscosity range is not the result of routine experimentation or optimization.

The mere fact that the reference could be modified does not render the modification obvious unless the prior art also suggests the predictable desirability of the modification, here no such predictable desirability of, for example, CO_2 foams with the claimed density, half-life, and viscosity is present. *See* M.P.E.P. § 2143.01. Therefore Applicants respectfully submit that the claimed invention is not obvious in view of *Osman* and request that the rejections be withdrawn.

III. PROVISIONAL DOUBLE PATENTING REJECTIONS

The Examiner has provisionally rejected the following claims on the ground of nonstatutory obviousness-type double patenting in view of *Osman*:

a) claims 1, 16, 19, 25 and 28 as being unpatentable over claims 1, 15, 16, and 37 in copending Application No. 10/522,527;

b) claims 1 and 19 as being unpatentable over claims 1, 9, 10, 13, and 14 in copending Application No. 10/890,267;

c) claims 1, 16 and 19 as being unpatentable over claims 1, 7, 9, and 15-17 in copending Application No. 11/128,265;

d) claims 1, 16 and 19 as being unpatentable over claims 1, 2, 7, 8, 16, and 17 in copending Application No. 11/914,190; and

e) claims 1, 16, 19, 25 and 28 as being unpatentable over claims 61, 64, and 68-70 in co-pending Application No. 11/225,860.

Applicants respectfully traverse these rejections. In the context of a double patenting rejection, the obviousness determination under 35 U.S.C. § 103 is modified in one important way. Unlike a § 103 obvious determination in which all the prior art reference teaches is relevant, only the claims and not the disclosure of the patent may be used to formulate a double patenting rejection. *See in re Braat*, 937 F.2d 589, 594 n.5, and 19 U.S.P.Q.2d 1289, 1293 (Fed. Cir. 1991); M.P.E.P. § 804.

None of the claims of the co-pending applications teach the claimed viscosity range. Therefore for all the reasons described above, none of the claims of any of these co-pending applications remedy the deficiencies of *Osman*. Applicants, therefore, respectfully submit that the double-patenting rejections in view of *Osman* be withdrawn.

In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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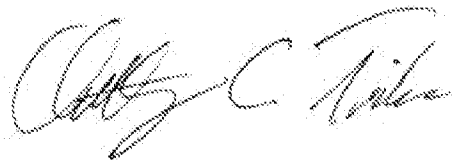

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By: _____

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